Guest Commentary

Monitoring Dietary Supplements and Medication Errors: USP Prescription for Safety

Miriam Reisman

Take of Opium powdered, two ounces.
Diluted alcohol, two pints.
Digest for ten days, and filter.

This simple recipe for opium tincture from the 19th century was considered quite an achievement in its time. Published by the United States Pharmacopeia (USP), early monographs like this one provided practitioners with the assurance that their patients were getting carefully prepared medicines and were using them correctly.

Since 1820, USP, a private, not-for-profit, volunteer-based organization, has been providing standards of quality for drug manufacturing. Opium tincture, or laudanum — in those days a common remedy for pain — was one of 217 natural medicines listed in the first pharmacopeia of the U.S. Today, USP provides standards for more than 3,800 prescription and nonprescription medicines, which pharmaceutical manufacturers are required to meet by federal regulation.

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The drugs are listed in a single-volume combination of the U.S. Pharmacopeia and the National Formulary (USP-NF) along with detailed descriptions of their properties, uses, dosages, and tests of purity.

“It’s a triumph of science that we know as much as we do about all of these drugs,” said Roger L. Williams, MD, executive vice president and chief executive officer of USP, during a recent visit to Jefferson Medical College of Thomas Jefferson University.

Dr. Williams, who came to USP in 2000, after nine years with the Food and Drug Administration (FDA), has continued a relationship with the FDA, he said, by “working with them in a sometimes separate, sometimes complementary, sometimes conflicting way.” A prime example of this synergy is the collaborative effort to ensure the quality of dietary supplements, which include vitamins, minerals, herbs, and botanical products.

Currently, a manufacturer is not required to register dietary supplement products with the FDA before producing or selling them. Instead, under the Dietary Supplement Health and Education Act (DSHEA) of 1994, a manufacturer is responsible for establishing its own guidelines to ensure that its products are safe and contain the ingredients listed on the label.

“You have to be careful with dietary supplements,” said Dr. Williams. “You’re taking a lot on faith.”

A study in the Journal of the American Medical Association found that an estimated 15 million adults take dietary supplements in addition to their prescription medications.1 In 2000, sales of dietary supplements reached an estimated $15.7 billion.2 Moreover, although some of these products may actually be beneficial, there is great potential for exaggerated claims, unpredictable composition, and toxicity. There is also a danger of interactions between dietary supplements and prescribed medications.

In an effort to inform and safeguard the growing number of consumers who use dietary supplements, USP has developed the Dietary Supplement Verification Program (DSVP), designed to complement the FDA regulation under DSHEA. The program allows companies to submit their products to USP for verification of quality and integrity. Products submitted to DSVP undergo extensive laboratory testing, comprehensive review of quality control documentation, and evaluation of compliance with USP and proposed FDA standards for “good manufacturing practices.” Products that meet these strict standards are awarded the USP-DSVP certification mark on their front container label.

Pharmavite was the first company to participate in the program by submitting its Nature Made product line through the DSVP certification process. The company expects its products to feature the USP-DSVP mark on retail shelves by the fall of 2002.

According to Dr. Williams, the DSVP is similar to the FDA approval letter that introduces drugs into the marketplace. “The DSVP mark with the words ‘USP Verified’ provides patients and practitioners with the assurance that these products have satisfied rigorous scientific criteria and assessments.”

In another effort to improve patient safety, Williams has spearheaded the MedMARx® program, an internal Internet-based performance tool that allows hospitals and health systems to anonymously report and track actual and potential medication errors in a standardized form.

In May 2002, USP released the MedMARx 2000 Report, which includes data for 41,296 errors reported by 184 health care facilities. The report, available to the public on USP’s Web site at www.usp.org, summarizes key medication error trends. For instance, the three most frequently reported medication error types were misses, improper doses or quantities, and the use of unauthorized drugs. The report also cites the two main causes of medication errors as performance deficit and failure to follow a procedure or protocol. In addition, the data showed that 97% of medication errors reported did not cause harm; of the 3% of the errors that did cause harm, some were serious and life-threatening.

“While just 3% of medication errors at hospitals result in a patient being harmed or dying, there are a lot of ‘near misses’ along the way,” said Dr. Williams, who hopes that by shedding light on these mistakes, USP’s MedMARx can help providers identify problem areas and develop more effective systems, resulting in higher-quality patient care.

In an era of increasing globalization, USP has also been promoting its standards and information activities on an international level, working closely with other governments and pharmacopeias through the Pan American Network for Drug Regulatory Harmonization program. Argentina, Brazil, and Mexico are currently in the process of either adopting or adapting the U.S. Pharmacopeia. “We hope this effort will serve as a model for other harmonization efforts around the world,” said Dr. Williams, who noted that 29 countries have already signed on to a European pharmacopeia.

And, what about a world pharmacopeia? Dr. Williams is optimistic. “The global community coming together in this way is a wonderful concept. I think we’ll see it in the future. I think it’s inevitable.”

REFERENCES

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